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10/693,698	10/27/2003	Farid Bruce Khalili	Ve 013	2291

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,698	Applicant(s) KHALILI, FARID BRUCE	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 43-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-42 and 61-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Species C in the reply filed on 6/26/2006 is acknowledged. The traversal is on the ground(s) that Figs. 4-6 are included in Species A. This is found persuasive.

It is noted that comparison of the claims with Figure 8-9 and 11-13 and the specification shows, however, that the species of Figure 8-9 and 11-13 does not have "said top end of said cup having a top opening and a generally cylindrical wall defining said top opening, said wall having at least two slots diametrically opposed to each other and extending downwardly from the uppermost portion of said wall; said generally cylindrical wall having an interior cylindrical wall surface that tapers generally outwardly in a downward direction from said uppermost portion; a cap associated with each cup being generally cylindrically shaped and having a pair of diametrically opposed tapered outer surfaces that taper radially outwardly, and having a pair of wing portions extending radially outwardly, said pair of wings further comprising vertically extending end surfaces; whereby with respect to each cup, said rod is received in each of said slots and said cap is positioned in said cup above said rod in a manner in which said tapered surfaces contact said interior wall surfaces and said vertically extending surfaces contact the outer surface of said generally cylindrical walls" (emphasis added) as required in claims 1, 11, and 20. These features are illustrated clearly in Species A, however, the elected species, Species C, does not appear to have these limitations.

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Thus, claims 1-26, 43-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/26/2006.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-42 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 27 and 34, lines 2-3, applicant positively recites part of a human, i.e. "a first fastener fixed to a first vertebra, a second fastener fixed to a second vertebra". Thus claims 27-42 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 30-34, 37-42, 61 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Nichols (U.S. Patent No. 6,090,111).

Nichols discloses a spinal rod system for bridging one or more adjacent vertebrae, the system comprising a first fastener capable of being fixed to a first vertebra; a second fastener capable of being fixed to a second vertebra; a rod extending at least between the first and second fasteners (see col. 1, paragraphs 3-4, and FIG. 1); a rod retention assembly (see FIG. 4, ref. #10) associated with each fastener for retaining the rod relative to each respective fastener; each the rod retention assembly comprising a cup (ref. #16 having an open top end and an open bottom end; the bottom end of the cup having a generally circular hole forming a bottom opening, the bottom opening being sized large enough to allow a portion of the respective fastener to pass through while retaining another portion of the fastener in the cup; the top end of the cup having a top opening and a generally cylindrical wall defining the top opening, the wall having at least two slots (see U-shaped slots, FIG. 2) diametrically opposed to each other and extending downwardly from the uppermost portion of the wall; the generally cylindrical wall having an interior cylindrical wall surface with at least two inverted shoulders (see FIG. 4), each inverted shoulder having a contact surface that is inclined in a direction radially outwardly from a center axis of the cup; a cap associated with each cup being generally cylindrically shaped and having at least two shoulders (see FIG. 4, ref. #56) extending radially outward and each having a shoulder with a

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contact surface that is inclined in a direction radially outwardly from a center of the cap; whereby with respect to each cup, the rod is received in each of the slots and the cap is positioned in the cup above the rod in a manner in which the respective contact surfaces of the cup and the cap contact each other. The system further comprises a sleeve ring (ref. #26) associated with each cup adapted to be positioned in the cup adjacent to the bottom opening and further adapted to support the associated fastener in the cup. The system further comprises a generally, inwardly tapered conical surface formed on the interior of the cup and surrounding the bottom opening, wherein the sleeve ring is positioned against the conical surface between the cup and the fastener in a manner in which the fastener is supported entirely by the sleeve ring. A generally, inwardly tapered conical surface is formed on the interior of the cup and surrounding the bottom opening, wherein the lower portion of the screw head rests on the conical surface in a manner in which the threaded shaft may be adjusted in angular orientation relative to the cup. The system further comprises a fastener head (ref. #22) associated with each fastener; and a seat spacer (ref. #42) adapted to rest on top of each the fastener head and to be positioned beneath the rod, thereby supporting the rod relative to the fastener. The top surface of each the fastener head is generally dome-shaped and each the seat spacer has a complementary contact surface that contacts the top surface of the respective fastener head in a manner permitting angular adjustment of the respective fastener relative to the seat spacer. Each fastener is a screw having a head of a diameter greater than the inner diameter of the sleeve ring (surface ridges, ref. #26), and having a threaded shaft of a diameter less than the inner diameter of the

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sleeve ring. The lower portion of the screw head is generally hemi-spherically shaped. The sleeve ring rests on the conical surface and the lower portion of the screw head rests on the sleeve ring in a manner in which the threaded shaft may be adjusted in angular orientation relative to the cup. Nichols further discloses a pedicle screw and rod retention system comprising a cup-shaped first retention member (ref. #16) having at least one slot for receiving a rod member therein, an open chamber for housing part of a fastener therein, a bottom opening from which part of the fastener extends, a top opening, and at least one inclined surface; and a second retention member (ref. #18) having at least one inclined surface that engages the inclined surface of the retention member. The system further comprises a rod engaging mechanism mounted in the second retention member that engages the rod (ref. #52).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-29 and 61-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Bono et al. (U.S. Patent No. 6,755,829).

Bono et al. disclose a spinal rod system for bridging one or more adjacent vertebrae, the system comprising a first fastener capable of being fixed to a first vertebra; a second fastener capable of being fixed to a second vertebra; a rod extending at least between the first and second fasteners (FIG 1c); a rod retention assembly associated with each fastener for retaining the rod relative to each respective fastener; each rod retention assembly comprising a cup (ref. #153) having an open top

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end and an open bottom end; the bottom end of the cup having a generally circular hole forming a bottom opening, the bottom opening being sized large enough to allow a portion of the respective fastener to pass through while retaining another portion of the fastener in the cup; the top end of the cup having a top opening and a generally cylindrical wall defining the top opening, the wall having at least two slots (see U-shaped slots, Fig 6b) diametrically opposed to each other and extending downwardly from the uppermost portion of the wall; the generally cylindrical wall having an interior cylindrical wall surface with at least two inverted shoulders (ref. #159b, FIG. 6c), each inverted shoulder having a contact surface that is inclined in a direction radially outwardly from a center axis of the cup; a cap associated with each cup being generally cylindrically shaped and having at least two shoulders (ref. #146) extending radially outward and each having a shoulder with a contact surface that is inclined in a direction radially outwardly from a center of the cap; whereby with respect to each cup, the rod is received in each of the slots and the cap is positioned in the cup above the rod in a manner in which the respective contact surfaces of the cup and the cap contact each other. A screw (col. 6, lines 23-27) is associated with each cap and adapted to be inserted through a screw hole (ref. #145) in the cap and further adapted to be tightened to apply pressure to the rod in order to lock the rod relative to the cup and to draw the respective contact surfaces against each other in a manner in which the generally cylindrical wall is biased radially inwardly. Each fastener is adapted to be locked with respect to its associated cup by progressive tightening of the respective screw. Bono et al. further disclose a pedicle screw and rod retention system comprising a cup-shaped

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first retention member (ref. #153, see FIG. 6b) having at least one slot for receiving a rod member therein, an open chamber for housing part of a fastener therein, a bottom opening from which part of the fastener extends, a top opening, and at least one inclined surface; and a second retention member (ref. # 140) having at least one inclined surface that engages the inclined surface of the retention member. The device further comprising a tensioning mechanism that selectively increases force between the inclined surfaces (col. 6, lines 23-27) and that biases a portion of the first retention member radially inwardly toward its central axis. A rod engaging mechanism mounted in the second retention member that engages the rod (bottom surface of ref. #140) engages the rod and that selectively increases force between the inclined surfaces and that selectively increases force between the inclined surfaces, and that biases a portion of the first retention member radially inwardly toward its central axis. The reference further states that the closure mechanism disclosed is adaptable to a "wide range of screws" (col. 2, lines 51-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 30-34 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bono et al. (U.S. Patent No. 6,755,829) in view of Barker et al. (U.S. Patent No. 6,280,442).

Bono et al. discloses the bone screw closure mechanism (including ref. #'s 140 and 153) disclosed as being adaptable to a "wide range of screws" (col. 2, lines 51-52. Bono et al. discloses the claimed invention except for all the particulars of the bone screw rod retention assembly, i.e. a sleeve ring adjacent a generally, inwardly tapered conical surface formed on the interior of the cup and surrounding the bottom opening, the fastener being supported entirely by the sleeve ring, the threaded shaft being adjusted in angular orientation relative to the cup, a seat spacer on top of the fastener head beneath the rod, the top surface of the fastener head being generally dome-shaped, the seat spacer having a complementary contact surface that contacts the top surface of the fastener head permitting angular adjustment of the respective fastener relative to the seat spacer, the fastener being a screw with a head of a diameter greater than the inner diameter of the sleeve ring and having a threaded shaft of a diameter less than the inner diameter of the sleeve ring, and the lower portion of the screw head being generally hemispherically shaped.

Barker et al. disclose a bone screw with a sleeve ring adjacent a generally, inwardly tapered conical surface formed on the interior of the cup and surrounding the bottom opening, the fastener being supported entirely by the sleeve ring, the threaded shaft may be adjusted in angular orientation relative to the cup, a seat spacer to rest on top of the fastener head beneath the rod, the top surface of each the fastener head

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being generally dome-shaped, and the seat spacer having a complementary contact surface that contacts the top surface of the fastener head permitting angular adjustment of the respective fastener relative to the seat spacer, each fastener being a screw with a head of a diameter greater than the inner diameter of the sleeve ring, and having a threaded shaft of a diameter less than the inner diameter of the sleeve ring, and the lower portion of the screw head is generally hemispherically shaped (see FIG. 7) in order to provide a bone screw that has improved strength and reduced size (col. 3, 3rd paragraph).

It would have been obvious to one of ordinary skill in the art to combine to bone screw closure mechanism of Bone et al. with the a bone screw with a sleeve ring adjacent a generally, inwardly tapered conical surface formed on the interior of the cup and surrounding the bottom opening, the fastener being supported entirely by the sleeve ring, the threaded shaft may be adjusted in angular orientation relative to the cup, a seat spacer to rest on top of the fastener head beneath the rod, the top surface of each the fastener head being generally dome-shaped, and the seat spacer having a complementary contact surface that contacts the top surface of the fastener head permitting angular adjustment of the respective fastener relative to the seat spacer, each fastener being a screw with a head of a diameter greater than the inner diameter of the sleeve ring, and having a threaded shaft of a diameter less than the inner diameter of the sleeve ring, and the lower portion of the screw head is generally hemispherically shaped in view of Barker et al. in order to provide a bone screw that has improved strength and reduced size.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



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